K042008

SEP - 3 2004

510(k) SUMMARY

In accordance with the provisions of the Safe Medical Device Act of 1990, Emageon UV., Inc. is providing a summary of safety and effectiveness information regarding the Ultravisual™ software.

1.1 Company Identification

Emageon UV, Inc.
131 W. Wilson Street
Suite 700
Madison WI 53703
Establishment Registration Number: 2135350
Contact: Inger Couture
Tel: 608 256 7775
Fax: 608 256 7779
Email: Inger.Hanson@emageon.com

1.2 Official Correspondent

Inger Couture
Director of Regulatory Affairs and Quality Assurance
Emageon UV, Inc.
131 W. Wilson Street
Suite 700
Madison WI 53703
Establishment Registration Number: 2135350
Tel: 608 256 7775
Fax: 608 256 7779
Email: Inger.Hanson@emageon.com

1.3 Date of Submission

June 29th, 2004

1.4 Device Name

Classification Name: Image Processing System, 21 CFR §892.2050, ProCode LLZ

Common/Usual Name: Picture Archiving and Communication System

Proprietary Name: Ultravisual™ (formerly Vortex™)

Cleared Device(s): Vortex™ , 510(k): K012097

1.5 Device Description and Intended Use

Emageon UV, Inc.'s Ultravisual™ software is integrated client-server software package comprised of features that were previously cleared in Vortex™ , 510(k): K012097. The main difference is that the software will now allow display of presentation quality digital mammography images, sent via the DICOM standard in order to make viewing of these images more convenient for the user.

1.6 Software Development

Emageon UV, Inc. certifies that the Ultravisual™ software is designed, developed, tested and validated in accordance with the same procedures as documented in the initial Vortex™ 510(k): K012097.

1.8 Safety and Effectiveness

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and indications for use.

The hardware components specified (and/or optionally supplied) are all "off the shelf" computer components.

Validation and Effectiveness:

As documented in the initial Vortex™ 510(k): K012097.

Substantial Equivalence:

The intended use of Emageon UV, Inc.'s Ultravisual™ software is substantially equivalent in the opinion of Emageon UV, Inc. to the feature set described in the original Vortex™ software, 510(k) K012097 and do not pose any new issues of safety and effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 3 2004

Emageon UV, Inc.
% Ms. Laura Danielson
Responsible Third Party
TÜV Product Service
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K042008
Trade/Device Name: UltraVisual™ Image Processing, Communication and Visualization Workstation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 19, 2004
Received: August 20, 2004

Dear Ms. Danielson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Device Name: Emageon UV, Inc., Ultravisual ™ Image Processing, Communication and Visualization Software Supporting Workstation

Indications for use:

Presentation quality mammography images sent via the DICOM standard can be displayed using features that are native to Emageon UV Inc.'s software. Other standard tools include intuitive tools for real-time pan, zoom, window/level and scroll; drag and drop series thumbnails for intuitive navigation; comprehensive set of grayscale and pseudo-color lookup tables; fully configurable magnifying glass; customizable window/level and zoom presets stored by modality and user; rotate images in 90-degree increments; flip image horizontally or vertically; customize display of on-screen user and patient demographics; sharpen, edge and blur filters; key image creation for communicating with other physicians, and multiple display support. Images can be displayed in any configuration or format the user specifies and associates with that specific user's profile. All display protocols and user configurable settings follow the user throughout the enterprise.

Lossy compressed or digitized screen film mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a FDA approved monitor that offers at least 5 Mpixel resolutions and other technical specifications reviewed and accepted by FDA.

Intended users of the image distribution system include radiologists, referring physicians, tertiary care physicians, medical technologists, and information technology professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____

David A. Jeppson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K042008